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| 09/204,236 | 12/03/1998 | GREGORY S. HAMILTON | AR218-X | 5251 |

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EXAMINER

CHANG, CELIA C

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 03/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/204,236

Applicant(s)
Hamilton et al.

Examiner
Celia Chang

Art Unit
1625



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 20, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 90-107 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 90-107 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

1. Response filed by applicants in Paper No. 27 dated Dec.20, 2001 have been entered and considered carefully.
2. The provisional rejection of claims 90-107 under the judicially created doctrine of obviousness type double patenting over claims 1-177 of SN 09/159,105 in view of Feghali is maintained for reason of record. Applicants argued that SN 09/159,105 encompassed a broader scope of compounds than the instant claims, thus, offered no predictability of the narrower scope of the instant claims. Please note that in absence of unexpected results, there is nothing unobvious in choosing some among many. In re Lemin 141 USPQ 814. A proper terminal disclaimer should be filed.
3. The provisional rejection of claims 90-107 under the judicially created doctrine of obviousness type double patenting over US '256 (claim 13), '449 (claims 20, 25, 29, 33), '957 (claims 17-20) in view of SN 09/159,105 (claims 1-177) and Feghali et al. is maintained for reason of record.

Applicants offered self contradictory arguments. On one hand applicants argued that "compounds used in the instant claims is distinguishable from the compounds in the cited references" (p.4, 3rd paragraph). On the other hand applicants argued that the instantly claimed compound having pyrrolidine ring joined to carboxylic acid isostere by a bond while the '256 or

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'957 claims have compounds pyrrolidine ring directly attached to the -COO-, -COS-, -CSS- moieties. Please note that "direct" attachment is a bond, thus, the instantly claimed compounds are overlapping with the issued claims.

The replacement of a functional moiety in a medicinal compound with its bioisostere is prima facie obvious since the definition of "bioisostere" (see King or Patani) is functional equivalency thus one having ordinary skill in the art would expect such replacement would result in reasonable success (see Patani p.3147). Applicants offered no rebuttal as to why a functional replacement of the carboxylate of the '256, '449, or '975 with a conventional bioisosteric moiety would not function in the similar manner as the teaching of the prior art. Please note that in absence of unexpected results, there is nothing unobvious in choosing some among many. In re Lemin 141 USPQ 814. A proper terminal disclaimer should be filed.

4. The rejection of claims 90-107 under 35 U.S.C. 112 second paragraph is maintained for reason of record.

Applicants argued that ordinary skilled person in the art would know what carboxylic acid and carboxylic acid isosteres are referring to. Please note that in the previous office action it was explained that the first determination must be "what" is included in the scope. Is it carboxylic acid or carboxylate ? Then whether the delineation of isosteres is encompassed by the "scope" of the claims. In other words, if the claims are drawn to carboxylic acids then a

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carboxylate isostere does not read on the base claim. Applicants must define the Markush elements to be consistent with the Markush term definition.

As pointed out by applicants that Patani et al. taught at Table 43 p.3168 both carboxylic acid and carboxylate isosteres. Please note that at the paragraph above the table wherein it was explained that the table is showing the physical chemical comparison that the “acid” isostere is similar to the acid while and its “anionic” isostere is similar to the anionic state. Thus, this table actually supports that carboxylic acid isostere is structurally analogous to the free acid while the carboxylate isostere is structurally analogous to the anionic state of the acid, i.e. distinct.

4. The rejection of claims 90-107 under 35 U.S.C. 103(a) over ‘256 in view of King or Patani is maintained for reasons of record.

Please note that the term “bioisostere” is defined by King or Patani as being “functional” equivalence. Thus, applicants offered no rebuttal as to why a functional replacement of the carboxylate of the ‘256 with a conventional bioisosteric moiety would not function in the similar manner as the prior art. Please note that the conventional delineation of “bioisostere” being functional equivalence provided both motivation and enablement to one having ordinary skill to modify a carboxylate functionality, thus, obviousness modification. One skilled in the art would have reasonable expectation of success based on King or Patani’s teaching. Obviousness under 35 U.S.C. 103(a) does not require absolute predictability. In re Kronig 190 USPQ 425.

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5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is (703) 308-4702. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner can be reached by fax. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-3922.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-4702.

CCPC/Chang
Feb. 26, 2002


Celia Chang
Primary Examiner
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